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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SHEN, WU CHENG WINSTON	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/770,418	LE MOUELLIC ET AL.	
	Examiner	Art Unit	
	Wu-Cheng Winston Shen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *71-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *71-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim amendments filed on March 13, 2007 have been received and entered. Claims 1-70 and 78-101 are cancelled. Claims 71, 76 and 77 are amended.

This application 10/770,418 filed on Feb. 04, 2004 is a CON of 10/639,754 08/13/2003 which is a CON of 08/466,699 06/06/1995 PAT 6,638,768, which is a CON of 08/301,037 09/06/1994 PAT 6,528,313, which is a CON of 08/048,056 04/19/1993 ABN, which is a CON of 07/598,679 12/19/1990 ABN. Relevant foreign applications are FRANCE PCT/FR90/00185 03/19/1990 and FRANCE 89 03630 03/20/1989.

Status of claims: Claims 71-77 are currently under examination.

Priority date of claims

1. The Non-Final office action mailed on 03/13/2007 noted that the applicants filed in the Oath or Declaration claiming priority dates of foreign applications FRANCE PCT/FR90/00185 03/19/1990 and FRANCE 89 03630 03/20/1989 in the instant application. The Examiner noted that the English translation of foreign applications FRANCE PCT/FR90/00185 03/19/1990 and FRANCE 89 03630 03/20/1989 has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

In the response filed on 3/13/2007, Applicant indicated that on December 19, 1990, a certified translation of Application No. PCT/FR90/00185 was filed in Application No. 07/598,679, to which this application claims priority. Applicant further indicates that on June 11, 1998, a certified translation of Application No. FR 89 03630 was filed in Application No.

08/301,037, to which this application claims priority. As provided in M.P.E.P. 201.14(b)(11), Applicant argues that no submission of further certified copies is required in the instant application and requests that the Office acknowledge that the required certified translations of the priority applications have been filed.

The Examiner thanks Applicant's clarification regarding certified translation of Application No. PCT/FR90/00185 and Application No. FR 89 03630 had been filed during the prosecution of the Parent applications, 07/598,679 and 08/301,037, of instant application. Accordingly, Applicant has perfected the requirement under 37 CFR 1.55 for claiming the foreign priority.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 71-77 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA insertion construct comprising a first DNA sequence and a second DNA sequence, wherein said insertion construct comprises two flanking sequences on either side of the insertion construct respectively homologous to two genomic sequences which are adjacent to a desired insertion site, and wherein said first DNA sequence encodes a first gene product that does not confer resistance to a selection agent involved in the selection of transformants, and said second DNA sequence encodes a second gene product that confers resistance to a selection agent involved in the selection of transformants, wherein the second DNA sequence is operatively linked to transcriptional and translational regulatory elements and

is located downstream of the first DNA sequence, wherein the expression of the second product that confers resistance to a selection agent involved in the selection of transformants, and wherein the first gene product is part or all of a receptor, does not reasonably provide enablement for a DNA construct comprising a second DNA that is not operatively linked to transcriptional control elements or for an insertion construct that is not flanked on either side by arms homologous to the site of insertion. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The nature of the instant invention is related to a procedure for specific replacement of a copy of a gene present in the genome of a recipient eukaryotic organism by the integration of a gene different from the inactivated gene (See parag. [0001] of instant application). The breadth of the claims: claim 71 and its dependent claims 72-75 encompass any DNA construct harbors any two genes from any organism, wherein one of the gene confers resistance to a selection agent involved in the selection of transformants and other gene encodes a gene product is part or all of a receptor; claim 76 encompasses any DNA construct harbors any two genes from any organism, wherein one of the gene confers resistance to a selection agent involved in the selection of transformants and other gene encodes a gene product is part of all of an interferon; claim 77 encompasses any DNA construct harbors any two genes from any organism, wherein one of the gene confers resistance to a selection agent involved in the selection of transformants and other gene encodes a gene product is part of all of an interleukin.

The specification discloses that the selection gene Neo^R, under the control of a promoter TK, was incorporated into the DNA to be inserted in order to make possible the selection of the transformants. The specification noted that the experiments described in the prior art implied a selection by means of the recipient gene (e.g. HPRT) or by means of the inserted gene (e.g. Neo^R) (See parag. [0015] of instant application). The specification further indicates that, in the prior art, the exogenous sequences on the vector thus serve both to target the integration site and to introduce the modification. Subsequent to homologous recombination, the modified gene is always found in its normal genetic environment (See parag [0016] of instant application).

In other words, the specification teaches homology sequences in the first gene as well as at the 3' end of the construct and a promoter for the second gene. The specification teaches homologous recombination such that the first gene inserts into an endogenous gene such that it is under the control of the promoter of said endogenous gene. However, the claims fail to recite the presence of any element that would result in the expression of a second gene, which is required to be structurally linked to the first gene. The specification teaches the use of an independent promoter in the construct such that the 2nd gene product is produced independent of the endogenous gene or the first gene. The intended use of the second gene is to screen for transformants, which cannot be performed unless the transcriptional and translational regulatory elements necessary for expression of the second gene are present. Therefore, there is lack of predictability of the DNA construct as claimed DNA to perform to the intended use disclosed in the specification regarding specific replacement of a copy of a gene present in the genome of a recipient eukaryotic organism by the integration of a gene different from the inactivated gene.

In view of the state of the art, the unpredictability in the art, and the lack of specific guidance and working examples in the specification, one of skill in the art would have to perform undue experimentation to make and use the claimed invention as recited in claims 71-77.

Claim Rejection - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 71-77 as amended remained rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Previous rejection is ***maintained*** for the reasons of record advanced on page 5 of the office action mailed on 12/13/06. It is noted that claim 68 has been cancelled, however, the same claim language has been restated in amended claims 71, 76, and 77.

Applicant's arguments

With respect to the aspect of the rejection regarding the recitation of phrase "wherein *the expression product* of said DNA construct comprises the second product that confers resistance to selection agent ---" referring to the first or the second gene product, Applicant argues that the amended claims recite "DNA construct," "first DNA sequence," and "second DNA sequence." As made clear by the language of the claims, the "DNA construct" comprises the "first DNA sequence" and the "second DNA sequence." The "first DNA sequence" encodes a "first gene product" and the "second DNA sequence" encodes a."second gene product." Thus, when the claims recite "the expression product of said DNA construct," that recitation is referring back to the entire DNA construct, and not specifically referring to either the "first DNA sequence" or "first gene product," or the "second DNA sequence" or "second gene product."

Response to Applicant's arguments

It appears that the Applicant's intention is to use the term "*the* expression product" to refer to both "the first gene product" and "the second gene product" expressed from "the DNA construct". However, it remains unclear because there are two gene products expressed from

two separate genes within the claimed DNA construct. Additionally, Taking into the consideration that RNA is also regarded as the expression product of DNA and the presence of polycistronic RNA (i.e. multiple genes transcribed as a single mRNA molecule) in prokaryotic cell and the presence of exons/introns in eukaryotic mRNA, it is unclear what is encompassed by the term "the expression product of said DNA construct" when there are more than one gene product. Furthermore, the claim fails to require that the two DNA sequences be operably linked. Thus, the first and second DNA sequences are not necessarily functionally linked and therefore, "the expression product of said DNA" could be referring to either the product of the first DNA sequence or the product of the second DNA sequence. In other words, as the claims do not set forth the limitation of any separating DNA sequences between the first and second DNA, such as a promoter or IRES, it cannot be determined from the claim if the first and second DNAs are in operable linkage with one another.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. The rejection of claims 68-70 under 35 U.S.C. 102(b) as being anticipated by Song et al. (Song et al., Accurate modification of a chromosomal plasmid by homologous recombination in human cells. *Proc Natl Acad Sci U S A.* 1987 Oct; 84(19): 6820-4, 1987), is ***withdrawn*** because claims 68-70 have been cancelled.

5. Claims 71 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Song et al. (Song et al., Accurate modification of a chromosomal plasmid by homologous recombination in human cells. *Proc Natl Acad Sci U S A.* 84(19): 6820-4, 1987, cited in the PTO-892 dated 12/13/2006 by Examiner).

Song et al. teach the consequences of modifying mammalian cellular DNA sequences by homologous recombination. A plasmid carrying a 248-base-pair deletion in the neomycin phosphotransferase (neo) gene was introduced into hamster and human cells. The integrated, defective neo gene was used as a target for modification by a second round of transfection with a plasmid carrying a different (283-base-pair) deletion in the neo gene. Recombinants resulting in an intact neo gene were selected by their G418 resistance phenotype. The best ratio of homologous to nonhomologous recombination events was about 1:80. Analyses of the functional neo genes in various independent cell lines establish that simple crossovers (single and double) generated the wild-type neo genes. More specifically, Song et al. teach a plasmid bearing first gene as bacterial guanine/xanthine phosphoribosyltransferase (gpt) gene and second gene as neomycin phosphotransferase (*neo*) gene (See Fig. 1, Song et al, and diagramed on page 7 of Non-Final office action mailed on 12/13/2006).

The substrates of guanine/xanthine phosphoribosyltransferase (gpt) are a purine base and *P*Rib-PP and the gpt enzyme convert the substrate into mononucleotide and pyrophosphate (See Figure 1, Vos et al. Structures of free and complexed forms of Escherichia coli xanthine-guanine phosphoribosyltransferase. *J Mol Biol.* 282(4): 875-89, 1998) and the molecular interactions at amino acid level between the enzyme gpt and its substrates (See Figure 3, Vos et al., 1998).

It is noted that the broadest and reasonable interpretation of "a receptor" recited in claim 71, "the first gene product is part of all of a receptor" reads on an enzyme as a receptor of the enzyme's substrate. Furthermore, improper metabolism of nucleic acid including purine (including xanthine and guanine) and pyrimidine can result in toxic effect leading to metabolic disorder such as Gout disease.

Thus, Song et al. 1987 clearly anticipates claims 71 and 72 of instant application.

6. Claim 76 is rejected under 35 U.S.C. 102(b) as being anticipated by Chernajovsky et al. (Chernajovsky et al., Efficient constitutive production of human fibroblast interferon by hamster cells transformed with the IFN-beta 1 gene fused to an SV40 early promoter. *DNA* 3(4): 297-308, 1984).

Chernajovsky et al. teach the construction of the plasmid pSVEIF, which harbors the interferon β1 (INF- β1) gene and the Ampicillin resistant gene (See Figure 1, Chernajovsky et al., 1984)

Thus, Chernajovsky et al., 1984 clearly anticipates claim 76 of instant application.

7. Claim 77 are rejected under 35 U.S.C. 102(b) as being anticipated by Lindenmaier et al. (Lindenmaier et al., Isolation of a functional human interleukin 2 gene from a cosmid library by recombination in vivo. *Gene* 39(1): 33-9,1985).

Lindenmaier et al. teach the construction of the plasmid pAN26-IL2, which harbors the interleukin 2 gene (IL2) and the kanamycin resistant gene (See Figure 1, Lindenmaier et al., 1985)

Thus, Lindenmaier et al., 1985 clearly anticipates claim 76 of instant application.

8. Claims 71, 72 and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by Sleckman et al. (Sleckman et al., Expression and function of CD4 in a murine T-cell hybridoma. *Nature* 328(6128): 351-3, 1987).

Sleckman et al. teach the retroviral vector construction MNST4, which harbors the CD4 gene (the receptor of infectious HIV) and the Neomycin resistant gene (See Figure 1, Sleckman et al., 1987). HIV is an infectious agent (as recited in claim 72) and the CD4 is a cellular receptor of HIV. Through interaction between which HIV envelope protein and CD4 receptor present on cell surface (an HIV receptor as recited in claim 75), the HIV can infect the cell.

Thus, Sleckman et al., 1987 clearly anticipates claims 71, 72 and 75 of instant application.

9. Claims 71 and 73 is rejected under 35 U.S.C. 102(b) as being anticipated by Petkovich et al. (Petkovich et al. A human retinoic acid receptor which belongs to the family of nuclear receptors. *Nature* 330(6147): 444-50, 1987).

Petkovich et al. disclose a *cDNA clone* encoding a retinoic acid receptor that binds

retinoic acid with high affinity (See abstract, Petkovich et al., 1987). Since a cDNA clone inherently teach that the clone harbors a selection agent involved in the selection of transformants as recited in claims 71 of instant application.

Thus, Petkovich et al., 1987 clearly anticipates claims 71, and 73 of instant application.

10. Claims 71 and 74 is rejected under 35 U.S.C. 102(b) as being anticipated by George et al. (George et al., Receptor density and cAMP accumulation: analysis in CHO cells exhibiting stable expression of a cDNA that encodes the beta 2-adrenergic receptor. *Biochem Biophys Res Commun.* 150(2): 665-72, 1988) as evidenced by Emorine et al. (Emorine et al., Molecular characterization of the human beta 3-adrenergic receptor. *Science* 245(4922): 1118-21, 1989).

It is noted that claim 71 recites, "wherein the first gene product is *part* or all of a receptor"and claim 74 depends from claim 71.

George et al. disclose a plasmid pUC13B2AR containing a beta 2-adrenergic receptor and the parental plasmid pUC harbors an antibiotics resistance gene (See Material and Methods, page 666, George et al., 1988). At the time of claimed priority of instant application, it was known that beta 2-adrenergic receptor shares high homology with beta 3-adrenergic receptor in mammals. For instance, Emorine et al. teach that human beta 3-adrenergic receptor shares 45.5% identical amino acid sequences of human beta 2-adrenergic receptor.

Thus, George et al. 1988 clearly anticipates claims 71 and 74 of instant application.

11. The rejection of claims 71-77 under 35 U.S.C. 102(e) as being anticipated by Kucherlapati et al. (U.S. Patent No. 6,514,752) is ***withdrawn*** because the effective filing date of

the instant application antedates that of Kucherplati as the priority application RFRANCE 89 03630 was filed on **03/20/1989** (See *Priority date of claims*).

Obviousness-type double patenting rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

It is noted that the Applicant did not address the provisional obviousness-type double patenting rejection in the response filed on 3/13/2007. Thereby, the provisional obviousness-type double patenting rejection is maintained of the record.

12. Claims 71-77 as amended of instant application No. 10/770,418 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 90, 99 and 108 of the other U.S. application of copending application No. 10/639,754. The instant application No. 10/770,418 is a continuation of the copending application No. 10/639,754.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 71-77 of instant application No. 11/115,868 are drawn to a DNA construct, encoding two distinct gene products, comprising a first DNA sequence and a second DNA sequence, wherein said first DNA sequence comprises a first coding sequence that encodes a first gene product that does not confer resistance to a selection agent involved in the selection of transformants, and said second DNA sequence comprises a second coding sequence that encodes a second gene product that confers resistance to a selection agent involved in the selection of transformants, wherein the second DNA sequence is downstream of the first DNA sequence, wherein the expression product of said DNA construct comprises the second product that confers resistance to a selection agent involved in the selection of transformants, in functional form, whereas claims 90, 99 and 108 of the other copending U.S. application No. 10/639,754 are drawn to the followings:

(i) A nucleic acid molecule comprising a recombinant recipient gene, wherein the recombinant recipient gene comprises: (A) a first DNA sequence of a recipient gene; (B) a second DNA sequence of the recipient gene, downstream of the first DNA sequence of the recipient gene; and (C) a DNA sequence heterologous with respect to the recipient gene; wherein

the heterologous DNA sequence is between the first DNA sequence of the recipient gene and the second DNA sequence of the recipient gene; wherein the heterologous DNA sequence comprises a first insertion DNA sequence and a second insertion DNA sequence; wherein the first insertion DNA sequence comprises a first coding sequence that encodes a first product that is not a marker involved in the selection of cells transformed with said nucleic acid molecule; and wherein the second insertion DNA sequence comprises a second coding sequence that encodes a second product that is a marker involved in the selection of cells transformed with said nucleic acid molecule, and a promoter allowing the expression of the second product in a cell transformed with said nucleic acid molecule (claim 90);

(ii) A nucleic acid molecule comprising a recombinant recipient gene, wherein the recombinant recipient gene comprises: (A) a first DNA sequence of the recipient gene; (B) a second DNA sequence of the recipient gene, downstream of the first DNA sequence of the recipient gene; and (C) a DNA sequence heterologous with respect to the endogenous recipient gene; wherein the heterologous DNA sequence is between the first DNA sequence of the recipient gene and the second DNA sequence of the recipient gene; wherein the heterologous DNA sequence comprises a first insertion DNA sequence and a second insertion DNA sequence; wherein the first insertion DNA sequence comprises a first coding sequence that encodes a first product that is not a marker involved in the selection of cells transformed with said nucleic acid molecule, and a regulatory sequence for regulating the expression of the first product; and wherein the second insertion DNA sequence comprises a second coding sequence that encodes a second product that is a marker involved in the selection of cells transformed with said nucleic

acid molecule, and a promoter allowing the expression of the second product in a cell transformed with said nucleic acid molecule (claim 99); and

(iii) A nucleic acid molecule comprising a recombinant recipient gene, wherein the recombinant recipient gene comprises: (A) a first DNA sequence of the recipient gene; (B) a second DNA sequence of the recipient gene, downstream of the first DNA sequence of the recipient gene; and (C) a DNA sequence heterologous with respect to the endogenous recipient gene; wherein the heterologous DNA sequence is between the first DNA sequence of the recipient gene and the second DNA sequence of the recipient gene; wherein the heterologous DNA sequence comprises a first insertion DNA sequence and a second insertion DNA sequence; wherein the first insertion DNA sequence comprises a regulatory sequence; and wherein the second insertion DNA sequence comprises a coding sequence that encodes a product that is a marker involved in the selection of cells transformed with said nucleic acid molecule, and a promoter allowing the expression of the product in a cell transformed with said nucleic acid molecule (claim 108).

Conclusion

13. No claim is allowed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Wu-Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the supervisory patent examiner, Peter Paras, can be reached on (571) 272-4517. The fax number for TC 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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4/01/07

Wu-Cheng Winston Shen, Ph. D.
Patent Examiner
Art Unit 1632